UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

THE AMERICAN TRADITION INSTITUTE ENVIRONMENTAL LAW CENTER,	)	
Plaintiff,	)	Civil Action No. 1:12-cv-1066 (AJT/TCB)
v.	)	
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

Before the Court is the defendant Environmental Protection Agency's ("EPA") Motion to Dismiss ("the Motion"), pursuant to rule 12(b)(1) or alternatively 12(b)(6) [Doc. No. 22].[1] Upon consideration of the Motion, the memoranda and exhibits in support thereof and in opposition thereto, and the arguments of counsel at a hearing on January 3, 2013, and for the reasons contained in this Memorandum Opinion, the Court finds that Plaintiff's Complaint fails to state a claim on which relief may be granted and the Court will GRANT the Motion to Dismiss.

I. BACKGROUND

In its complaint, the American Tradition Institute ("ATI")[2] alleges that the defendant, EPA, failed to adequately inform participants in a study known as the CAPTAIN study of the

[1] The Complaint was filed on September 21, 2012. An Emergency Motion for a Temporary Restraining Order [Doc. No. 7] was then filed on September 27, 2012, and denied, after hearing, on October 9. [Doc. No. 17].

[2] There are two plaintiffs listed the caption. One is the Environment Law Center, about which nothing is alleged in the Complaint, and appears to be the advocacy arm for the other named plaintiff, ("ATI"), which is alleged to be a 501(c)(3) organization and which describes its

life-threatening health risks associated with their exposure to particulate matter ("PM") air pollution, all in violation of what is referred to as the Common Rule, which regulates human experimentation.[3] Based on this claim, the plaintiff seeks a wide range of declaratory and injunctive relief, including an immediate halt to the EPA's CAPTAIN study "and any other EPA human experimentation which intentionally exposes human subjects . . . to 'fine particles' . . . ."[4]

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mission as advancing "rational, free-market solutions to America's land, energy, and environmental challenges." ATI is alleged to be based in Burke, Virginia, and claims to have members throughout the U.S., including in Virginia [Compl., ¶ 3, Doc. No. 1].

[3] The Common Rule is a set of regulations promulgated by the EPA, as well as other federal department and agencies, that govern the ethical and scientific conduct of government sponsored research with human participants. EPA has codified the Common Rule in its regulations at 40 C.F.R. § 26.101 *et. seq.* Among its core requirements are:

> 1. That people who participate as subjects in covered research are selected equitably and give their fully informed, fully voluntary written consent; and
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> 2. That proposed research be reviewed by an independent oversight group referred to as an Institutional Review Board (IRB), and approved only if risks to subjects have been minimized and are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result.

See EPA, *Human Subjects of Research (the "Common Rule")*, at http://www.epa.gov/oppfead1/guidance/cr-require.htm (last visited Jan. 31, 2013).

[4] ATI also seeks the following additional relief:

- A declaration that EPA failed to provide legally effective informed consent to subjects participating in PM 2.5 studies.
- A prohibition on any further use of expenditures to conduct the CAPTAIN study.
- An Order that EPA to suspend use of the University of North Carolina Medical Institutional Review Board ("IRB").
- A prohibition on EPA's relying on data resulting from any research involving intentional exposure of any human subject to PM 2.5.
- A stay of any implementation of Clean Air Act ("CAA") rules regulating fine particulate matter until the Agency can review its processes for promulgating rules to ensure that "EPA does not rely in any fashion upon illegal human experimentation."
- An Order for follow-up monitoring of all human subjects that have been exposed to PM 2.5 (requested for the first time in Plaintiff's Reply).

On November 21, 2013, the defendant filed its Motion on the grounds that (1) this Court lacks subject matter jurisdiction because the EPA has not engaged in any agency action that is subject to judicial review in this Court; and (2) plaintiffs do not have standing to assert the claims alleged in the Complaint.[5] ATI has opposed that motion and the Court held a hearing on the Motion on January 3, 2013, following which it took the matter under advisement.

A. Jurisdiction based on final agency action.

ATI contends that this Court has jurisdiction under the APA.[6] In that regard, ATI first contends that because its members are "adversely affected or aggrieved" by "agency action" within the meaning of a "relevant statute," i.e., the National Research Act, this Court has jurisdiction under § 702 ("Right of Review"). Section 702 provides, in pertinent part, that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review

[5] ATI contends that EPA has improperly filed its motion to dismiss pursuant to Rule 12(b)(1), rather than 12(b)(6), as required, because this Court's jurisdiction necessarily requires a merits determination of ATI's claim. Given the jurisdictional challenge that EPA has raised, the Court concludes that EPA's motion to dismiss is properly considered under Rule 12(b)(1). In any event, the Court finds that the EPA has adequately invoked, in the alternative, both rules for its motion, that the facts and information submitted outside of the allegations of the Complaint may be considered under either rule in connection with the jurisdiction and standing issues, and that there is no need to determine which rule is the proper procedural vehicle for the Court to consider the merits of EPA's motion.

[6] The EPA contends that to the extent there is judicial review based on final agency action, the Clean Air Act ("CAA") vests exclusive jurisdiction for that purpose in an appropriate Court of Appeals, not this or any other District Court. ATI disputes this contention on the grounds that it does not claim that EPA's challenged conduct violated any proscriptions under the CAA and its jurisdictional provisions are therefore inapplicable to ATI's challenges in this action. Because this Court concludes that there is neither agency action nor final agency action that would confer jurisdiction on this Court under the APA, as ATI contends, there is no need to consider whether this Court, as opposed to a Court of Appeals, would have jurisdiction to review such agency action.

thereof." Alternatively, ATI contends that if there is no "relevant statute" for the purposes of § 702, this Court has jurisdiction under § 704 ("Actions reviewable"), which provides:

> Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.

Under both theories, ATI relies on §§ 703 and 706(1), (2)(D).[7]

1. **The is no "Final Agency Action"[8]**

Where no other statute provides a private right of action, the "agency action" necessary for judicial review must be "final" agency action. *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 61 (2004). Based on the record before the Court, this Court finds that the challenged EPA conduct does not constitute "final agency action" for the purpose of the APA.

Section 551(13) defines "agency action" as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13). ATI claims that the "agency action" definition is satisfied based on EPA's "failure to act." This position fails for several reasons. First, ATI claims that EPA committed a "failure to act," as that term is used in § 551(13), when it failed to adequately comply with an "agency rule," viz, the

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[7] 5 U.S.C. § 703 ("Form and venue of proceeding"); 5 U.S.C. §§ 706(1) & (2)(D) ("To the extent necessary . . . [t]he reviewing court shall-- (1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be-- (D) without observance of procedure required by law.")

[8] Plaintiff's alternative jurisdictional contentions notwithstanding, during oral argument on EPA's motion, ATI took the position that there must be "final agency action" before this Court may review the challenged aspects of the CAPTAIN study. Because ATI's jurisdiction claim under § 702 essentially conflates with its claim of statutory standing under § 702, the Court discusses the merits of that claim within the context of the standing issue, discussed *infra.*, and for the reasons stated therein, rejects ATI's claim that for standing purposes under § 702 its members have been "adversely affected or aggrieved" because they fall within the "zone of interests" protected under the National Research Act. For the same reasons, the Court rejects its jurisdictional claim based on the same contention.

Common Rule.[9] More specifically, ATI claims that EPA failed to act: (1) when it failed to provide adequate disclosures of all reasonably foreseeable health risks, however low;[10] and (2) when the Agency failed to notify the Institutional Review Board ("IRB") that the CAPTAIN study was being conducted in violation of the Common Rule.

ATI's construction of the term "failure to act" is at odds with the Supreme Court's controlling construction of that term, as articulated in *Norton.* There, the Supreme Court ruled that "'[t]he failure to act' is . . . properly understood as a failure to take agency action – that is, a failure to take one of the agency actions (including their equivalents) earlier defined in § 551(13)." *Norton*, 542 U.S. at 62. Here, ATI does not claim that EPA failed in its duty to promulgate or issue an agency rule, only that it failed to comply with one. This kind of conduct does not constitute agency action. *See Am. Civ. Liberties Union v. Nat'l Security Agency,* 493 F. 3d 644, 678 (6th Cir. 2007) [hereinafter "*ACLU*"] (finding that a failure to comply with the Foreign Intelligence Surveillance Act is not "agency action.").

Second, even assuming that some of these alleged "failures to act" constitute "agency action" under § 551(13), the alleged "agency action" is not "final" agency action for the purposes of § 702. Agency action is "final" when it satisfies two requirements: "First, the action must mark the 'consummation' of the agency's decision making process-it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal citations omitted). The following factors are relevant to determining whether these factors are met: "(1) whether the action is a definitive

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[9] EPA's codification of the Common Rule is at 40 C.F.R. part 26.

[10] As summarized at the hearing on January 3, 2013, ATI claims that the undisclosed health risks include (1) the risk of death within 24 hours of a subject's exposure to PM 2.5; and (2) that a subject's exposure to PM 2.5, which contains carcinogens, results in an increased risk of cancer.

statement of the agency's position; (2) whether the action had the status of law and immediate compliance with its terms was expected; [and] (3) whether the action had a direct impact on the day-to-day business of the plaintiff. . . ." *Wollman v. Green*, 603 F. Supp. 2d 879, 884-85 (E.D. Va. 2009) (quoting *Trinity Indus., Inc., v. Herman*, 173 F.3d 527, 532 (4th Cir. 1999)).

The EPA's alleged "failure[s] to act" do not satisfy either requirement of a final agency action under § 702. ATI appears to concede this point but nonetheless argues that EPA's "approval" of the CAPTAIN research study is evidence of final agency action.[11] However, that conduct is only the exercise of the EPA's discretion to approve a research study reviewed by the IRB, authorized under § 26.120 of the Common Rule ("The department or agency head will evaluate all applications and proposals involving human subjects . . . [o]n the basis of this evaluation, the department or agency head *may* approve or disapprove the application or proposal. . . ." (emphasis added)). At a minimum, this action does not involve conduct by which "...'rights or obligations have been determined,' or from which 'legal consequences will flow.'"[12] *See Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d. 852, 858 (4th

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[11] To support this position, ATI points to the letter dated March 6, 2012, from Warren Lux, EPA Human Subjects Research Review Official [Doc. No. 14-1, Ex. 5].

[12] The lack of finality in Mr. Lux's letter for the CAPTAIN study is highlighted by the role played by the IRB. As the Common Rule suggests, the IRB, a non-governmental agency that is separate and apart from the EPA (or any other government agency), has primary responsibility for reviewing proposed research and ensuring that the requirements of informed consent required under the Common Rule (*see* 40 C.F.R. § 26.116) are satisfied. 40 C.F.R. § 26.109(a)-(b). One element of informed consent is providing the subject with "a description of any reasonably foreseeable risks or discomforts[,]" and the IRB's process for reviewing any proposed research project requires them to evaluate this factor, among many others. The rules prohibit the IRB from approving a project unless it determines consent has been, or will be, satisfactorily obtained. *See* 40 C.F.R. § 26.116(a). IRB approval is defined as "the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements." 40 C.F.R. § 26.102(h). For these reasons, before approving a research proposal the IRB—not the EPA (or other federal agency)—is responsible for determining that the following requirements have been satisfied: (1) risks to subjects are minimized; (2) risks to subjects are reasonable in relation to anticipated

Cir. 2002) (holding that an EPA report that classified environmental tobacco smoke as a known human carcinogen was not a final agency action because it did not determine legal rights and obligations.)

B. ATI does not have standing

As discussed above, the APA authorizes suit by "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute. . . ." 5 U.S. C. § 702. Based on this provision, ATI claims that it has both the required organizational standing and the required prudential standing.

The question of standing "involves both constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise." *Bennett*, 520 U.S. at 162. In order to establish standing with respect to ATI's challenges to EPA's alleged conduct, ATI must therefore satisfy the "case or controversy" requirement of Article III and establish that any alleged injuries fall within the "zone of interests" that Congress intended to protect (so-called prudential standing).

ATI claims that it has organizational standing based on the standing of its individual members. An organization may establish standing based on its members, and "[i]n attempting to secure relief from injury to itself the association may assert the rights of its members' associational ties." *Warth v. Seldin*, 422 U.S. 490, 511 (1975). A three-part test is used to determine whether an association has such organizational standing: "(1) [whether] its own members would have standing to sue in their own right; (2) the interests the organization seeks to

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benefits, if any, to subjects; (3) the selection of subjects is equitable; (4) informed consent will be sought from each prospective subject or the subject's legally authorized representative; (5) informed consent will be appropriately documented; (6) the research plan makes adequate provision for monitoring the data collected to ensure the subjects' safety; (7) protecting privacy rights of subjects; and (b) protecting vulnerable subjects from coercion or undue influence. 40 C.F.R. § 26.111.

protect are germane to the organization's purpose; and (3) neither the claim nor the relief sought requires the participation of individual members in the lawsuit." *Md. Highways Contractors Ass'n, Inc. v. Maryland*, 933 F.2d 1246, 1251 (4th Cir. 1991) (citing *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333 (1977)); *see also Mainstream Loudoun v. Bd. of Trs. of Loudoun Cnty. Library*, 2 F. Supp. 2d 783, 791 (E.D. Va. 1998) (applying the three-part test).

The Court concludes that ATI does not have standing to bring its claims since none of its members have been shown to have suffered constitutionally sufficient "injury in fact" or have interests that bring them within the "zone of interests" Congress intended to protect.

1. Article III standing

To satisfy the "case" or "controversy" requirement of Article III, which is the "irreducible constitutional minimum" of standing, a plaintiff must demonstrate that: (1) it has suffered an "injury in fact," (2) the injury is "fairly traceable" to the actions of the defendant, and (3) the injury will likely be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992); *Valley Forge Christian Coll. v. Am. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471-472 (1982). In support of its standing claim, ATI has filed sworn declarations for three of its members: Landon Huffman, Steven J. Millroy, and David Schnare. All three have affirmed their deep seated concerns and outrage over human experimentation generally, and of EPA's use of human subjects for PM studies specifically. The plaintiffs have also described how the EPA studies have harmed them and their reputations, and how the relief sought will address their suffering and distress.[13]

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[13] *See* Milloy's declaration at ¶ 4 ("After learning of how the U.S. Environmental Protection Agency (EPA) was risking the lives and health of human study subjects and was failing to honestly represent the nature of the human experimentation that is the subject of the instant matter, I was appalled by this inhumanity."); at ¶ 5 ("I am deeply aggrieved by the kind of human experimentations being conducted by [EPA] and will not be relieved until it stops).

ATI acknowledges that in order to establish "injury in fact" it must show "an invasion of a legally protected interest which is 'concrete and particularized' and 'actual and imminent, not conjectural or hypothetical.'" *Lujan*, 504 U.S. at 560 (internal quotations and citations omitted). "Abstract injury is not enough. . . . [T]he injury or threat of injury must both be 'real and immediate. . . .'" *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-102. ATI also acknowledges that general emotional distress is insufficient to establish a legal violation. *See Humane Soc'y of U.S. v. Babitt*, 46 F.3d 93, 98 ("[G]eneral emotional harm, no matter how deeply felt, cannot suffice for injury-in-fact purposes."). ATI argues, however, that the declarations of Huffman, Schnare, and Millroy establish sufficient injury in fact because they have demonstrated an

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See Schnare's declaration at ¶ 4 ("I more than abhor current government experimentation on humans for the purposes of determining the effect of poisons. It is not only that such activity dishonors those who should have been the last to have suffered in such a manner, it sickens me. It angers me...."); ¶ 5 ("When I learned of the human experimentation at issue in this case, I realized a duty to challenge EPA's misanthropic activities, if for no other reason than to preserve my own legacy of having worked assiduously on behalf of public health."); ¶ 7 ("After learning of how EPA failed to honestly represent the nature of the human experimentation that is the subject of the instant matter, I was appalled that UNC Biomedical IRB review process failed to conduct the kind of independent review necessary to ensure the representations by EPA were not only true by complete and fully reflected EPA's knowledge about the poisons with which they intended to force into the lungs of unsuspecting and inadequately informed victims. As an alumnus of the University [of North Carolina], I am deeply upset at its failure and it adds to my great angst and the emotional harm I suffer from the on-going illegal human experimentation."); ¶ 8 ("the relief sought...will significantly ameliorate my suffering and will help return honor to the memory of [his relative who died in the Holocaust] and all those who died at the hands of the 'Doctors from hell'").

See Huffman declaration at ¶ 5 ("Since learning that the EPA considers the gases to which I was exposed were lethal, I have been distraught and experienced emotional distress, such as fear of becoming ill or dying. My health is of utmost importance to me and I am disturbed by the fact that my health is in jeopardy more than I realized at the time I voluntarily agreed to participate in these studies. As a result of these studies I am distressed that I may not be able to provide for my wife and family, in the short-term as well as long-term."); ¶ 6 ("I am also distressed that others may suffer the way I do if they participate in ingoing studies. No one should be falsely and unknowingly exposed to a lethal gas and only by stopping this human experimentation will I be relieved of my continuing concern that others not suffer what I now do.")

increased risk of health problems in Huffman's case, and harm to personal, political, and professional reputation in Schnare's case. The plaintiff also argues that, while in general "social moral indignation" is not an injury that can be addressed in federal court, the social moral indignation experienced by all three these members in this case arises out of their knowledge that the Common Rule has been violated. For that reason, ATI contends that their harmed interests are within the "zone of interests" protected by the National Research Act and the Common Rule and therefore are constitutionally sufficient injury under Article III and sufficient to satisfy any prudential standing requirement.

The Court finds and concludes that none of these injuries are sufficient to support standing. First, Huffman claims an increased risk of cancer as a result of his participation in an EPA PM study (but not the CAPTAIN study) in November 2006 and May 2007. An increase in health risks can constitute injury in fact, but such claims must be reasonable and fact based, not based on unsubstantiated conjecture. Injuries cannot be solely based on self-imposed subjective apprehension, free of government coercion, restraint, or compulsion. *See ACLU*, 493 F.3d at 662. Here, Huffman has not claimed he in fact suffers from any specific medical condition that has been exacerbated, or that there has been a medical diagnosis that he faces an increased risk of future complications as a result of his participation. Without any intent to minimize Huffman's emotional distress, the Court must conclude that the record does not establish that Huffman has sufficiently demonstrated an injury in fact for standing purposes.[14]

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[14] In this regard, the Court has reviewed in detail the information provided to potential study participants about the amount of PM that participants have been and would be subjected to, how those exposure levels compare with PM exposure that the general public experiences, what is known about the health risks associated with the various levels of possible exposure, the actual incidence of adverse health effects on study participants, the information included in the IRB application, and the monitoring done during the studies.

The Court likewise finds Schnare's injuries insufficient as a matter of law to establish injury in fact. Nowhere does Schnare claim that his personal or professional reputation has actually been harmed in a concrete, objective way, by the ongoing EPA research. He has not been subjected to any government regulation, restraint, or coercion. Rather, much like Huffman, his objection to the experimentation is a self-imposed, subjective apprehension. *See ACLU*, 493 F.3d at 662. The effect of the challenged conduct on Millroy is even more removed from the CAPTAIN studies than Huffman and Schnare. Millroy, who owns and maintains "two websites dedicated to exposing government excess and dishonest science," does not claim to have had any involvement in the CAPTAIN study or to have been affected in his website activities as a result of the challenged conduct. Based on the current record, ATI has failed to sufficiently show that one or more of its members are directly affected by the challenged EPA conduct apart from the members' special interest in the subject. *See Lujan*, 504 U.S. at 563.

Nor can injury in fact be predicated upon the "social moral indignation" of its members generally, or these three members in particular. In this regard, ATI argues that "[t]he National Research Act parentage of the Common Rule create [sic] a zone of interest that includes any citizen aggrieved by Agency non-compliance with the Common Rule." Pl's Resp., at 7. Indeed, according to ATI, "EPA has an obligation to the society at large to meet its obligations to social justice. Any person adversely aggrieved by EPA's failure to meet that obligation is within the zone of interest of the relevant statute and has a right of judicial review under 702." *Id.*, at 12. In making this argument, ATI effectively concedes that for standing purposes the outrage felt by its members cannot be distinguished from the outrage that any member of society might feel upon learning that EPA has violated the Common Rule. But ATI can point to no expressions of congressional intent to extend enforcement of the Common Rule to "society at large." ATI

invokes the Belmont Report's reference to obligations to "society at large," EPA's reference in certain publications to "social justice," and other references to various agency publications. *See Dr. Tr. of Jan. 3, 2013, Hrg.*, at 37:21-23 ("in fact this [lawsuit] could be a citizen suit by any citizen because the intent of these rules is to protect not just the individual or the researcher, but society at large."). But the Court would be hard pressed to find in any of these references any Congressional intent to extend constitutional standing to any member of the general public to enforce compliance with the Common Rule, something ATI implicitly recognizes is necessary to establish its standing with respect to its challenge to the CAPTAIN study. Pl.'s Resp., at 3 (citing 5 U.S.C. § 702). *See Lujan*, 504 U.S. at 573-574 ("We have consistently held that a plaintiff raising only a generally available grievance about government – claiming only harm to his and every citizen's interest in proper application of the Constitution and laws, and seeking relief that no more directly and tangibly benefits him than it does the public at large – does not state an Article III case or controversy.") For these reasons, the Court concludes that none of the harmed interests of ATI's member are within the "zone of interests" protected under a "relevant statute." Finally, even if the ATI members could have established injury in fact, ATI has not satisfied other requirements for organizational standing, including that the alleged injuries are fairly traceable to the challenged EPA conduct and that the requested relief would directly address their claimed injuries.

For these reasons, the Court finds and concludes that ATI does not have Article III standing.

2. Prudential Standing

Section 702 also imposes a prudential standing requirement in addition to Article III's injury in fact requirement. *See, e.g., Ass'n of Data Processing Serv. Org., Inc. v. Camp*, 397 U.S.

150, 152 (1970). ATI claims in this regard that the harm it has sustained falls within the "zone of interests" protected under the National Research Act and the studies that have been conducted pursuant to that Act. For the same reasons that this Court has concluded that ATI and its members are not "adversely affected or aggrieved . . . within the meaning of a relevant statute," as required under § 702, the Court finds and concludes that ATI cannot establish the requirements of prudential standing.

CONCLUSION

For the above reasons, the Court concludes that it does not have subject matter jurisdiction over ATI's claims and that ATI does not have standing to bring such claims. The Motion to Dismiss [Doc. No. 22] is GRANTED.

An appropriate Order will issue.

/s/
Anthony J. Trenga
United States District Judge

Alexandria, Virginia
January 31, 2013